

CLAIMS

1. A chimeric empty capsid of the infectious bursal disease virus (IBDV), characterized in that it is constituted by assembly of (i) IBDV pVP2 proteins and (ii) fusion proteins comprising a region A constituted by the IBDV VP3 protein bound to a region B constituted by a heterologous polypeptide comprising a polypeptide of interest.
2. Capsid according to claim 1, wherein said region B is bound to the amino-terminal region of IBDV VP3, or alternatively to the carboxy-terminal region of IBDV VP3.
3. Capsid according to claim 1, wherein said polypeptide of interest is a polypeptide useful in vaccination, therapy or diagnosis.
4. Capsid according to claim 1, wherein said region B comprises a single polypeptide of interest.
5. Capsid according to claim 1, wherein said region B comprises two or more polypeptides of interest.
6. Capsid according to claim 1, wherein said fusion protein comprises a region A bound to a single region B.
7. Capsid according to claim 1, wherein said fusion protein comprises a region A bound to two regions B, equal or different, one of them bound to the amino-terminal region of VP3 present in region A, and the other one to the carboxy-terminal region of VP3 present in region A.
8. Capsid according to claim 7, wherein said regions B contain more than one polypeptides of interest equal to or different from one another.
9. Capsid according to claim 1, wherein said fusion protein further comprises, a linker polypeptide located between said regions A and B.

10. A nucleic acid, said nucleic acid having a nucleotide sequence which comprises the nucleotide sequence encoding for the fusion protein defined in anyone of claims 1 to 9.

11. A nucleic acid, said nucleic acid having a nucleotide sequence which comprises
5 (i) a nucleotide sequence comprising the open reading frame corresponding to the IBDV VP3 protein and (ii) a nucleotide sequence comprising the open reading frame of one or more heterologous polypeptides comprising one or more polypeptides of interest.

12. Nucleic acid according to claim 11, further comprising (iii) a nucleotide sequence
10 comprising the open reading frame corresponding to the IBDV pVP2 protein.

13. A gene construct comprising a nucleic acid according to claim 10 or 11.

14. A gene construct comprising a nucleic acid according to claim 12.
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15. An expression system selected from:

a) an expression system comprising a first gene construct according to claim 13, operatively bound to transcription, and optionally translation, control elements, and a second gene construct, operatively bound to transcription, and optionally translation, control
20 elements; said second gene construct comprising a nucleotide sequence comprising the open reading frame corresponding to the IBDV pVP2 protein; and

b) an expression system comprising a gene construct according to claim 14, operatively bound to transcription, and optionally translation, control elements.

25 16. Expression system according to claim 15, said expression system being selected from plasmids, bacmids, yeast artificial chromosomes (YACs), bacteria artificial chromosomes (BACs), bacteriophage P1-based artificial chromosomes (PACs), cosmids, or viruses, which optionally contain a heterologous replication origin.

30 17. A host cell containing a nucleic acid according to anyone of claims 10 to 12, or a gene construct according to anyone of claims 13 or 14, or an expression system according to anyone of claims 15 or 16.

18. A host cell, said cell having been transformed, transfected or infected with an expression system according to any of claims 15 or 16.

19. Host cell according to claim 17 or 18, said cell being selected from a mammal
5 cell, an avian cell, an insect cell and a yeast.

20. A process for the production of chimeric empty capsids of the infectious bursal disease virus (IBDV) according to anyone of claims 1 to 9, comprising culturing a host cell according to anyone of claims 17 to 19, and, if desired, recovering said chimeric empty
10 IBDV capsids.

21. Process according to claim 20, wherein said host cell is an insect cell, comprising the steps of:

- 15 a) preparing an expression system selected from (I) and (II), wherein:
- expression system (I) is constituted by a recombinant baculovirus containing a gene construct according to claim 14; and
 - 20 - expression system (II) is constituted by a first recombinant baculovirus containing a gene construct encoding for the IBDV pVP2 protein, and a second recombinant baculovirus containing a gene construct according to claim 13;
- 25 b) infecting insect cells with said expression system prepared in step a);
- c) culturing the infected insect cells obtained in step b) under conditions allowing the expression of recombinant proteins and their assembly to form chimeric empty IBDV capsids; and
- 30 d) if desired, isolating and optionally purifying the chimeric empty IBDV capsids.

22. A process according to claim 20, wherein said host cell is a yeast, comprising the steps of:

- 5 a) preparing an expression system constituted by a plasmid containing a gene construct according to claim 14;
- b) transforming yeast cells with said expression system prepared in step a);
- 10 c) culturing the transformed yeasts obtained in step b) under conditions allowing the expression of recombinant proteins and their assembly to form chimeric empty IBDV capsids; and
- d) if desired, isolating and optionally purifying the chimeric empty IBDV capsids.

15 23. The use of a gene expression system according to anyone of claims 15 or 16 for producing chimeric empty IBDV capsids according to anyone of claims 1 to 9.

24. The use of chimeric empty capsids of the infectious bursal disease virus (IBDV) according to anyone of claims 1 to 9 in the manufacture of a medicament.

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25. Use according to claim 24, wherein said medicament is a vaccine.

26. Use according to claim 24, wherein said medicament is a gene therapy vector.

25 27. A vaccine comprising a therapeutically effective amount of chimeric empty capsids of the infectious bursal disease virus (IBDV) according to anyone of claims 1 to 9, optionally together with one or more pharmaceutically acceptable adjuvants and/or vehicles.

28. A vaccine according to claim 27, useful to simultaneously protect animals or
30 humans against infection caused by two or more disease-causing infectious agents.

29. A gene therapy vector comprising a chimeric empty capsid of the infectious bursal disease virus (IBDV) according to anyone of claims 1 to 9.